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Executive Office of Environmental Affairs

DEP **Department of Environmental Protection**

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Commissioner

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Suggested Outline, Content and Format of Phase II Human Health Risk Assessment Scope of Work

Policy #WSC-140-91

Attached is a copy of the Department of Environmental Protection Policy #WSC-140-91.

This policy provides guidance on the human health risk assessment component of the Massachusetts Contingency Plan Phase II Scope of Work, and should be considered an extension of the *Guidance for Disposal Site Risk Characterization and Related Phase II Activities - In Support of the Massachusetts Contingency Plan* (MA DEP, 1989). This guidance should be considered applicable to any disposal site for which a risk characterization is required persuant to the Massachusetts Contingency Plan (310 CMR 40.00). As always, the level of detail necessary in the Scope should reflect the complexity of the disposal site.

James C. Colman — 5/13/91
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Assistant Commissioner
Bureau of Waste Site Cleanup
Date

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SUGGESTED OUTLINE, CONTENT AND FORMAT OF PHASE II HUMAN HEALTH RISK ASSESSMENT SCOPE OF WORK

This guidance is provided for the risk assessment component of the Massachusetts Contingency Plan Phase II Scope of Work, and should be considered an extension of the *Guidance for Disposal Site Risk Characterization and Related Phase II Activities - In Support of the Massachusetts Contingency Plan* (MA DEP, 1989).

This document presents the suggested content, format and level of detail of the Phase II *Scope of Work*. It should be considered applicable to any disposal site for which a risk characterization is required per the Massachusetts Contingency Plan (310 CMR 40.000).

The Massachusetts Department of Environmental Protection (MA DEP) anticipates that the utilization of this guidance by a Potentially Responsible Party (PRP), DEP staff and the environmental consulting community will result in risk assessment reports which are of higher quality, less costly, and are completed in a more timely manner.

This guidance was completed at a time when other relevant Departmental policies were under development. Some of these policies (such as the *Determination of Foreseeable Future Use Policy*), when completed, may require revisions to this *Scope of Work Guidance*.

SUGGESTED OUTLINE, CONTENT AND FORMAT

OF THE
MASSACHUSETTS CONTINGENCY PLAN
PHASE II HEALTH RISK ASSESSMENT

SCOPE OF WORK

May 1991

SUGGESTED OUTLINE, CONTENT AND FORMAT OF PHASE II HUMAN HEALTH RISK ASSESSMENT SCOPE OF WORK

The following is a list of activities which should be addressed in the Phase II Human Health Risk Assessment Scope of Work[1]. In the *Scope of Work*, some activities should actually be **done**, while other activities should be presented as things which **will be done** in the Phase II Risk Assessment Report.

I. CURRENT AND FUTURE USE OF THE SITE

A. The *Scope of Work* should identify the current and reasonably foreseeable use of the disposal site and the surrounding area and provide justification for that use.

For example, the current use of the site is for light manufacturing activity. The site is surrounded by residential property, but access to the site by residents is limited by fencing. Groundwater is not currently used for any purpose, as all homes and manufacturing facilities are connected to a public supply with a remote source. Future use of the site and surrounding area expected to remain the same as current use.

The scope should be approved only if the project manager concurs with the identified uses(s).

B. The *Scope of Work* should clearly indicate that separate evaluations will be conducted for current land use and foreseeable land use unless they are identical.

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[1]Beyond the health risk characterization, the MCP requires characterization of risk of harm to safety, public welfare and the environment. There is little policy or guidance available for these risk characterizations. Basically, site conditions should be compared to any applicable or suitably analogous safety, welfare and environmental standards, guidelines and policies. Massachusetts groundwater quality standards and surface water quality regulations are the most obvious components of this evaluation.

Nuisance odors and property values are considered among welfare issues, and fire, explosion, and physical dangers are considered among the safety issues.

II. HAZARD IDENTIFICATION

A. The *Scope of Work* should identify the oil or hazardous materials (OHM) which will be carried through the quantitative risk assessment and those which have been detected but will not be carried through the risk assessment. The *Scope* should state that the Report will provide justification for each OHM thus eliminated from the assessment.

B. The *Scope of Work* should state that the Report will identify the extent of release of all OHM, identify all Exposure Point Concentrations to be used in assessing risks, and provide Toxicity Profiles or descriptive toxicity summaries of OHM carried through the risk assessment. Comprehensive toxicity profiles would be required only for OHM which have no health-based standards or guidelines.

III. DOSE-RESPONSE

For sites to be evaluated using risk assessment Method 3.b.[2], for risk-based guidelines developed under Method 3.a., and for Method 3.a. evaluations which are driven by total site risk policies, the *Scope of Work* should say that the Risk Assessment will present the dose-response information for the OHM evaluated in the assessment. To be consistent with the MCP, EPA Reference Doses and EPA Cancer Potency Values should be used when available. Doses associated with DEP's Allowable Threshold Concentrations (ATCs) are to be used to evaluate threshold health effects from inhalation exposures when there is not an EPA Inhalation Reference Dose.

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[2]Risk assessment Methods 1,2, 3.a. and 3.b. are described in the Department's *Guidance for Disposal Site Risk Characterization and Related Phase II Activities - In Support of the Massachusetts Contingency Plan* (MA DEP, 1989). The characterization of the risk of harm to human health is required by the MCP in 310 CMR 40.545 (3)(g).

IV. EXPOSURE ASSESSMENT

A. The *Scope of Work* should identify:

1. All Potential Human Receptor Groups;
2. All Potential Exposure Points for each Receptor Group and the activities resulting in exposure;
3. All Potential Exposure Routes at each Potential Exposure Point for each Receptor Group;
4. Frequency of Exposure for each Potential Receptor at each Exposure Point;
5. Duration of each Exposure Event for each Potential Receptor at each Exposure Point.
6. Duration of each Exposure Period for each Potential Receptor at each Exposure Point. The Report should indicate whether the exposure is lifetime, chronic, subchronic or acute in nature and provide justification for any period not evaluated.

Critical factors in conducting total site risk calculations are the identification of receptors and the development of exposure profiles for these receptors. The general philosophy should be that a single receptor is exposed at all identified exposure points unless that is clearly impossible or highly unlikely.

For example, a resident adjacent to a facility might be exposed both as a child and also subsequently as an adult. That same receptor might also be exposed in his/her backyard, in his/her home, and perhaps infrequently at the facility.

B. The *Scope of Work* should contain a narrative description of all appropriate exposure profiles. An exposure profile details all of the current and reasonably foreseeable exposures for each theoretical receptor. Such a profile describes a receptor and how that receptor is and might be exposed in the foreseeable future. Specific information contained in an exposure profile includes body weight, exposure points, media contacted, exposure routes, and the frequency, duration and intensity of exposure. Thus for Method 3.b. evaluations (and for Method 3.a. evaluations which are driven by total site risk policies), total site risks are to be calculated for ***each*** receptor group for which an exposure profile is developed, for **both** the current land use and the foreseeable future land use.

C. The *Scope of Work* should contain a chart similar to Table 1, which describes a sample exposure profile.

D. The *Scope of Work* should state that the Risk Assessment will present the exposure parameters and equations used to estimate risk in sufficient detail to enable all calculations to be verified by Departmental reviewers.

E. The *Scope of Work* should identify any **permanent** *Short Term Measures* or *Interim Measures* (such as soil excavation and removal) which have been completed and which will be considered in the development of the exposure profiles. **Nonpermanent** *Short Term Measures* or *Interim Measures* (e.g. fences, gravel cover, filtration systems) are considered to be temporary in nature, and should *not* be considered in the development of the exposure profiles. In other words, the potential for exposure should be assessed and the potential risks should be characterized as if those measures had not been taken.

V. RISK CHARACTERIZATION

A. The *Scope of Work* should tentatively identify the method for health risk assessment (1,2, 3.a. or 3.b.) and provide justification for that choice. Method 2 is currently not an option.

B. The *Scope of Work* should identify, in a narrative format, potentially applicable or suitable analogous public health standards which will be used in the risk assessment (e.g. Massachusetts MCLs are considered applicable or suitably analogous standards for drinking water exposures.). The actual numerical criteria should not be given in the *Scope of Work*.

C. For Method 3.a., potentially applicable or suitably analogous guidelines and policies which will be used in the risk assessment should be identified in a narrative format (e.g. AALs are considered applicable or suitably analogous guidelines for exposure to contaminants in ambient air.). The actual numerical criteria should not be given in the *Scope of Work*.

For sites evaluated by Method 3.a. only, if a standard or guideline is lacking for any OHM, the *Scope of Work* should say that guideline(s) will be developed and proposed per the MCP (310 CMR 40.545(3)(g)(3.a.). Any such guideline would be associated with a dose no

greater than 20% of an RfD or other allowable dose specified or approved by the Department and would be associated with an excess lifetime cancer risk (for lifetime exposure) no greater than one in one million.

D. For sites evaluated by Method 3.b., the *Scope of Work* should state that daily doses or average concentrations (when appropriate) will be identified for each receptor at each exposure point via each exposure route.

E. The *Scope of Work* should briefly describe **how** health risk will be characterized for the disposal site.

For Method 3.b., the *Scope of Work* should state that:

1. Exposure Point Concentrations for all Receptor Groups will be compared to the applicable or suitably analogous standards identified in the Report.
2. A Screening Hazard Index will be calculated for each Receptor Group, and, within each receptor group, for all appropriate Exposure Periods (lifetime, chronic, subchronic and/or acute) identified in the Exposure Profile. The Hazard Indices will be compared to the MCP Total Site Non-Cancer Risk Limit. In the event that any Screening Hazard Index exceeds the MCP Total Site Non-Cancer Risk Limit, a more detailed Hazard Index may be performed based upon the contaminants' mechanism(s) of action and/or target organ(s).
3. A Total Site Cancer Risk will be calculated for each Receptor Group, and the Total Site Cancer Risks will be compared to the MCP Total Site Cancer Risk Limit.
4. A clear summary of all Hazard Indices and Total Site Cancer Risks for each Receptor Group for both current use(s) and foreseeable use(s) will be presented in the Risk Assessment Report.

VI. UNCERTAINTY ANALYSIS

The *Scope of Work* should state that uncertainties in the risk assessments will be identified and discussed (especially for Method 3.b. sites).

Uncertainties include the adequacy of the sampling plan, the quality of the analytical data, the accuracy of any modeling procedures, assumptions concerning the frequency, duration and magnitude of exposures, the availability and accuracy of toxicity data, and the treatment of available analytical data.

VII. CONCLUSIONS

The *Scope of Work* should state that conclusions concerning the need for remediation will follow the requirements set forth in the Massachusetts Contingency Plan (310 CMR 40.545(3)(i)) and will be based on the information contained in the *entire* Phase II Report, including the human health risk assessment.

TABLE 1 - EXPOSURE PROFILES (WITHOUT EXPOSURE POINT CONCENTRATIONS)
Values in this Table are examples ONLY! They are NOT recommended values.

CURRENT LAND USE

RECEPTOR	EXPOSURE POINT	ACTIVITY	MEDIUM	EXPOSURE ROUTE	FREQUENCY	DURATION	DURATION
NEIGHBORHOOD RESIDENT *	SITE	PLAY/SPORTS	SOIL	INGESTION	1DAY/WK **	LIFETIME	1 DAY/EVENT
			SOIL	DERMAL	1DAY/WK **	LIFETIME	1 DAY/EVENT
			DUST	INHALATION	1DAY/WK **	LIFETIME	6 HR/EVENT
	HOUSE	WATER USE	DRINKING WATER	INGESTION	7 DAY/WK	LIFETIME	1 DAY/EVENT
				DERMAL	7 DAY/WK	LIFETIME	1 DAY/EVENT
				INHALATION	7 DAY/WK	LIFETIME	18 HR/EVENT
	HOUSE	HOUSEHOLD ACTIVITY	INDOOR AIR (FROM G.W.)	INHALATION	7 DAY/WK	LIFETIME	18 HR/EVENT
	POND	CATCH AND EAT FISH	FISH	INGESTION	1 DAY/MO	LIFETIME	1 DAY/EVENT

* - INCLUDES CHILDHOOD AND ADULT AGE GROUPS. HAZARD INDEX BASED ON CHILD EXPOSURES. CANCER RISK BASED ON LIFETIME EXPOSURE.
** - CHILDREN EXPOSED 1 DAY/WEEK MARCH THRU NOVEMBER
- ADULTS EXPOSED 1 DAY/WEEK MARCH THRU NOVEMBER

EXAMPLE

FUTURE LAND USE

RECEPTOR	EXPOSURE POINT	ACTIVITY	MEDIUM	EXPOSURE ROUTE	FREQUENCY	DURATION	DURATION
ON-SITE RESIDENT *	YARD	PLAY/YARD WORK	SOIL	INGESTION	5 DAY/WK **	LIFETIME	1 DAY/EVENT
			SOIL	DERMAL	5 DAY/WK **	LIFETIME	1 DAY/EVENT
			DUST	INHALATION	5 DAY/WK **	LIFETIME	6 HR/EVENT
	HOUSE	WATER USE	DRINKING WATER	INGESTION	7 DAY/WK	LIFETIME	1 DAY/EVENT
				DERMAL	7 DAY/WK	LIFETIME	1 DAY/EVENT
				INHALATION	7 DAY/WK	LIFETIME	18 HR/EVENT
	HOUSE	HOUSEHOLD ACTIVITY	INDOOR AIR (FROM G.W.)	INHALATION	7 DAY/WK	LIFETIME	18 HR/EVENT
	POND	CATCH AND EAT FISH	FISH	INGESTION	1 DAY/MO	LIFETIME	1 DAY/EVENT

* - INCLUDES CHILDHOOD AND ADULT AGE GROUPS. HAZARD INDEX BASED ON CHILD EXPOSURES. CANCER RISK BASED ON LIFETIME EXPOSURE.
** - CHILDREN EXPOSED 5 DAYS/WEEK MARCH THRU NOVEMBER
- ADULTS EXPOSED 2 DAYS/WEEK MARCH THRU NOVEMBER

ATTACHMENT

COMPLETENESS CHECKLIST - PHASE II RISK ASSESSMENTS

_____ Were current and reasonably foreseeable future uses of the site and the surrounding environment identified?
_____ Were background levels of oil or hazardous materials identified?
_____ Was a Method selected (1, 2, 3.a., or 3.b.)?
_____ Is the selection appropriate?

HAZARD IDENTIFICATION

_____ Are all detected compounds addressed and carried through the assessment?
_____ If chemicals of concern are used, is justification provided?

EXPOSURE ASSESSMENT

_____ Are all receptors identified?
_____ Are all routes of exposure identified?
_____ Are all exposure point concentrations identified?
_____ Are all contaminated media identified?

DOSE RESPONSE (Method 3.a. guideline development and Method 3.b.)

_____ Are carcinogenic effects addressed?
_____ Are non-carcinogenic effects addressed?

CHARACTERIZATION OF RISK OF HARM TO PUBLIC HEALTH

_____ Were applicable or suitably analogous public health standards identified?

METHOD 3.a.

_____ Were public health guidelines and policies identified?
_____ Were exposure point concentrations compared to public health standards, guidelines and policies?

METHOD 3.b.

_____ Was Total Site Cancer Risk calculated?
_____ Was the Hazard Index calculated?
_____ Were exposure point concentrations compared to standards?

CHARACTERIZATION OF RISK TO SAFETY, PUBLIC WELFARE AND THE ENVIRONMENT

_____ Characterization of risk of harm to safety.
_____ Characterization of risk of harm to public welfare.
_____ Characterization of risk of harm to the environment.
_____ Were applicable or suitably analogous environmental standards, guidelines and policies identified?

CONCLUSIONS

_____ Were conclusions made concerning the need for remediation?

NOTE: COMPLETENESS IS NOT EQUAL TO APPROVABILITY